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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 64, 65, 67 – 76 and 78 - 83 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,120,308 to Hess.

In regard to claims 64, 65, 67 – 70, Hess discloses an intracorporeal device (14) comprising an elongated member having a longitudinal length and means for causing a **substantially** linear change in bending stiffness over the entire longitudinal length of the elongated member, wherein the elongated member has a plurality of tapered segments (16, 18, 20) configured to produce the **substantially** linear change in bending stiffness over the length of the member. It is noted that the term “substantially” is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. In re Nehrenberg, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). See MPEP 2173.05(b). The Examiner considers the plurality of tapered segments producing a **substantially** linear change in bending stiffness over the length of the member in that the tapered sections reduce the cross sectional area of the member substantially linearly and that bending stiffness is directly proportional to cross sectional area. The length of the elongated member has a continuously changing taper angle (Figure 1) producing a curvilinear profile that is configured to produce the substantially linear change in bending stiffness over said length. Each tapered segment has a substantially constant taper angle. The elongate core member comprises at least 3 to about 100 tapered segments (16, 18, 20; Col. 8, lines 1 – 3). The elongated

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core member comprises a material with changing hardness in a longitudinal direction configured such that the change in hardness produces a substantially linear change in bending stiffness along the length of the core member in that the material decreases in cross sectional area along the length of the core member. The member tapers distally to a more flexible distal portion (20).

In regard to claims 71 – 83, Hess discloses a guidewire comprising an elongated core member having at least one longitudinal section having a **substantially** linear change in bending stiffness over the length thereof. It is noted that the term “substantially” is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. In re Nehrenberg, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). See MPEP 2173.05(b). The Examiner considers the plurality of tapered segments producing a **substantially** linear change in bending stiffness over the length of the member in that the tapered sections reduce the cross sectional area of the member substantially linearly and that bending stiffness is directly proportional to cross sectional area. Even though Hess may not expressly disclose the formula set forth in claim 71, the guidewire of Hess is sufficient to read on the claim. It is respectfully noted that the claim only requires that the diameter be defined by the formula for a single value of length L. Since C is a constant that depends on the boundary conditions of the longitudinal section, C can arbitrarily be defined so that the formula will be true for at least one point at a distance of L from a starting position of any taper. Therefore, the longitudinal section of Hess has a tapering diameter defined substantially by the formula set forth in claim 71 for one value of L. Similarly, the longitudinal section has a moment of inertia defined substantially by the formula set forth in claim 78 for one value of L. The core member is formed of NiTi alloys (Col. 6, lines 5 – 8). A flexible body (22) is disposed about and secured to a distal core section. The guidewire comprises at least 3 to 100 tapered segments (16, 18, 20). The guidewire comprises at least 5 to 100 tapered segments (Col. 8,

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lines 1 – 3). The proximal and distal core sections are coated with a lubricious coating (Col. 8, lines 8 – 10).

Response to Arguments

3. Applicant's arguments filed 10/7/09 have been fully considered but they are not persuasive.

Applicant asserts that Hess fails to disclose a member having a longitudinal length and means for causing a substantially linear change in bending stiffness over the entire longitudinal length.

However, the Examiner disagrees. As Applicant points out, the means are a plurality of tapered segments. Hess discloses a plurality of tapered segments (16, 18, 20; Col. 8, lines 1 – 3). The Examiner considers the plurality of tapered segments producing a ***substantially*** linear change in bending stiffness over the length of the member in that the tapered sections reduce the cross sectional area of the member substantially linearly and that bending stiffness is directly proportional to cross sectional area.. Additionally, it is noted that the term “substantially” is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. In re Nehrenberg, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). See MPEP 2173.05(b).

While the tapered segments disclosed by Hess may not produce an actual linear change in bending stiffness, the Examiner asserts that because bending stiffness is directly proportional to cross sectional area, and the tapers reduce ***substantially*** linearly, that a ***substantially*** linear change in bending stiffness exists. Furthermore, because Hess discloses a plurality of tapered segments being formed of the same material as disclosed by Applicant, that the tapered segments include the same properties as claimed. Additionally, Applicant asserts that Hess fails to disclose a core member being defined by the formulas as claimed. It is respectfully noted that the claim only requires that the diameter be defined by the formula for a single value of length L. Since C is a constant that depends on the boundary conditions of the longitudinal section, C can arbitrarily be defined so that

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the formula will be true for at least one point at a distance of L from a starting position of any taper. Therefore, the longitudinal section of Hess has a tapering diameter defined substantially by the formula set forth in claim 71 for one value of L . Similarly, the longitudinal section has a moment of inertia defined substantially by the formula set forth in claim 78 for one value of L . It is also noted that L can be infinitely small.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736